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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,748	12/11/2000	Julio Boza	112701 036	7778

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EXAMINER
MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
1653	9

DATE MAILED: 11/05/2002

Due: 2/5/03

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,748	BOZA, JULIO	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

ACKNOWLEDGMENT TO AMENDMENT, REMARKS, STATUS OF THE APPLICATION AND CLAIMS

1. The amendment and remarks filed 10/9/01 are acknowledged, entered and considered. In view of Applicant's request claims 1-10 have been amended and claims 11-16 have been added. Thus, claims 1-16 are now pending in the application. The objection to the title, abstract, improper multiple dependency, and the rejection under 35 U.S.C. 101, and the partial rejection under 35 U.S.C. 112, second paragraph, and the rejections under 35 U.S.C. 102(b) over the prior art of record are withdrawn in view of Applicant's amendment and remarks filed 10/9/01. However, the partial rejection under 35 U.S.C. 112, second paragraph and the objection to trademarks are maintained.

OBJECTIONS TO TRADEMARKS AND THEIR USE

2. The use of the trademarks or tradenames "Nutricomp®Immun", "Reconvan®", "Glutasorb®", "PEPAMEN®", "PROPEPTIDES®" and "ALFARE®" have been noted in this application. Further, some of the trademarks or tradenames have not been capitalized, they should be capitalized whenever they appear and be accompanied by the generic terminology. Although, the use of trademarks are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in a manner which might adversely affect their validity as trademarks.

Further, the specification which specifies the generic terminology should include published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred by the trademarks. These description requirement are made because the nature and composition of articles denoted by trademarks can change and affect the adequacy of the disclosure.

3. It is noted that Applicant has amended the rejected claims under 35 U.S.C. 112, second paragraph partially as suggested by the Examiner, rendering the rejection pertaining thereto moot. Thus, the rejection for the claims which have been amended according to the Examiner's suggestion have been withdrawn, but, issues in the claims which have not been amended and have been argued by Applicant are maintained for the same reasons discussed on the previous Office action as reiterated below:

CLAIM REJECTIONS-35 U.S.C. § 112 2nd PARAGRAPH

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and newly submitted claims 11-16 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are indefinite in the recitation "a protein mixture which....." because it is not clear to what kind of protein mixture the claims are referring. Appropriate clarification is required.

The syntax of claim 7 is unclear and indefinite in the recitation "...having a molecular weight of less than 1000 Da.....", ".....having a molecular weight of 1000 Da to 5000 Da....." and ".....having a molecular weight of greater than 5000 Da" because the claim recites three different ranges in one claim. If Applicant intends to claim the preferred range as well as the broad range, then, the Office recommends the use of three dependent claims claiming the recited ranges. Also, the claim is indefinite and confusing in the recitation "less than ....." and "greater than...." because it is unclear as to the lower range/limitation by the recitation "less than" since the lower limitation/range could be from zero to recited maximum range/limitation. Similarly, the recitation of "greater than...." makes the claim indefinite because it is unclear as to higher range/limitation since the higher range/limitation could be from the recited range/limitation up to infinity. Thus, amendment of the claim to recite definite range/limitation is suggested.

ARGUMENTS ARE NOT PERSUASIVE

5. Applicant's arguments filed 10/9/01 have been fully considered but they are not persuasive. With respect to Applicant's arguments that Applicant believe that all trademarks recited in the application have been capitalized. To the extent that the Patent Office believes that there are any trademarks or tradenames, that are not capitalized, Applicant requests that the

Patent Office point out same is noted. Applicant's attention is directed for example, to page 2, line 26 that "Nutricomp®Immun", "Reconvan®", "Glutasorb®" are not capitalized, they should be capitalized whenever they appear and be accompanied by the generic terminology. Although, the use of trademarks are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in a manner which might adversely affect their validity as trademarks.

Further, the specification which specifies the generic terminology should include published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred by the trademarks. These description requirement are made because the nature and composition of articles denoted by trademarks can change and affect the adequacy of the disclosure.

CLAIMS REJECTION-35 U.S.C. § 112 2nd PARAGRAPH

6. The rejection of claims 1-10 and newly submitted claims 11-16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has argued that the phrase "a protein mixture which stimulates the amino acid profile of whey protein" is understood by those skilled in the art to refer to a mixture of proteins, protein hydrolyzate and/or free amino acids which have the same or similar amino acid composition as whey protein. Thus, no further clarification is required for this portion of

independent claims 1-3. Also, Applicant's argument that claim 7 does not recite three different ranges in one claim because the hydrolyzed whey is comprised of free amino acids and different types of peptides and the peptides are characterized by their molecular weight is not persuasive. Contrary to Applicant's arguments, claims 1-3 as amended the "protein mixture....." does not refer to protein hydrolyzate and/or free amino acids which have the same or similar amino acid composition as whey protein as argued by Applicant. Rather, it defines a functional limitation by stating that a protein mixture which stimulates the amino acid profile of whey protein. Thus, one of skill in the art would understand from the functional limitation for the term"a protein mixture..." to encompass protein hydrolyzate and/or free amino acids which have the same or similar amino acid composition as whey protein as argued by Applicant.

With respect to claim 7, it the Examiner's position that the clam still recites three different ranges in one claim. Further, the claim is indefinite and confusing in the recitation "less than about....", "less than ....." and "greater than...." because it is unclear as to the lower range/limitation by the recitation "less than" since the lower limitation/range could be from zero to recited maximum range/limitation. Similarly, the recitation of "greater than...." makes the claim indefinite because it is unclear as to higher range/limitation since the higher range/limitation could be from the recited range/limitation up to infinity.

Thus, for the reasons discussed above and the definiteness of the claim is important to allow others who wish to enter the market place to ascertain the boundaries of protection that are provided by the claims. See *Ex parte Kristensen,* 10 USPQ 2d. 1701, 1703 (PTO Bd. App. &

Inter. 1989). Hence, in order to obviate the above rejection, it is suggested again that Applicant amend the claim to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

7. Applicant's amendment, arguments with respect to the rejections under 35 U.S.C. 102(b) over the prior art of record have been considered but deemed to be moot in view of the new ground of rejections necessitated by Applicant amendment.

NEW GROUND OF REJECTION

CLAIM REJECTIONS-35 U.S.C. § 102(b)

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ballevre et al. (U.S. 5,849,335).

Claims 1-16 are directed to methods for increasing glutamine by using whey protein or a protein mixture administered to a patient to increase plasma glutamine concentration in stressed mammal (claim 1), to increase muscle glutamine concentration in mammal (claim 2), to use as nutritional/therapeutic composition to a mammal suffering from injured, diseased or under-

developed intestines (claim 3), wherein the mammal is a pre-term infant having an under-developed intestine (claim 4), wherein the protein is hydrolyzed (claims 5 and 6) and having the various molecular weights recited in claim 7, wherein the protein source provide energy of the nutritional composition thereof (claims 8, 11 and 14), wherein the nutritional composition further includes a lipid source (claims 9, 12 and 15) and wherein the nutritional composition includes a carbohydrate source (claims 10, 13 and 16) .

Ballevre et al. disclose a nutritional composition comprising a protein source including whey protein and a protein mixture having the amino acid profile of whey protein which is administered to stressed patients to increase the plasma glutamine concentration, or administered as nutritional support for increasing muscle glutamine concentration in athletes after exercise, or administered to patients suffering from injured or diseased intestines or to maintain the physiological functions of the intestines particularly in under-developed intestines (e.g., a pre-term infant or babies). See e.g., abstract; col. 1, lines 44-50; col. 3, lines 1-25; col. 6, lines 13-38; claims 24, 26-28 and 30. Thus, clearly meeting the limitations of claims 1-4.

The prior art discloses the use of nutritional composition wherein the whey protein is hydrolyzed whey protein, the protein source provides about 10% to about 30% of the energy of the nutritional composition, the nutritional composition further includes a lipid source which provides about 20% to about 40% of the energy of the nutritional composition and the lipid source comprises a mixture of medium chain and long chain fatty acids and as such meet the limitations of claims 5-6, 8-9, 11-12 and 14-15. The reference discloses also a nutritional

composition which further includes a carbohydrate source which provide about 35% to about 60% of the energy of the nutritional composition and a such meets the limitations of claims 10, 13 and 16. See e.g., col. 2, lines 46-64; col. 4, lines 4-56 and Examples 2-4. Hence, the reference clearly discloses the administration of nutritional composition which contains whey protein (or a protein mixture which stimulates its acid profile) as a protein source for increasing glutamine levels in plasma or muscle of a stressed patient, pre-term baby or athlete. Thus, as the whey protein hydrolysate comprises glutamine and it is used fro nutritional purposes, it increases plasma glutamine concentration in mammals, increases muscle glutamine concentration in mammals, and provides treatment to patients suffering from injured, diseased or underdeveloped intestines.

In regard to the molecular weight of claim 7, the molecular weight is not disclosed in the prior art; however, the claim as drafted recites any hydrolysate whey protein having a molecular weight which is less than 1,000 Da or having a molecular weight of 1,000 Da to 5,000 Da or a molecular weight greater than 5,000 Da; and does not define the molecular wight as functional limitation, rather, the claim defines the molecular weight as properties of the hydrolysate whey protein formulation. Thus, it is the Examiner's position that the hydrolysate whey protein formulations of the prior art would have the same molecular weight as claimed (i.e., less than 1,000 Da or greater than 5,000 Da) because the claim does not identify specific protein(s) having a molecular weight greater than 5,000 Da, or fragments thereof having a molecular weight less than 1,000 Da, and as such, the molecular weight is an inherent properties of the prior art protein.

Therefore, in the absence of evidence to the contrary, the nutritional formulation and its use thereof as disclosed by the reference anticipates claims 1-16 as drafted.

9. Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/54985.

Claims 1-16 are directed to methods for increasing glutamine by using whey protein or a protein mixture administered to a patient to increase plasma glutamine concentration in stressed mammal (claim 1), to increase muscle glutamine concentration in mammal (claim 2), to use as nutritional/therapeutic composition to a mammal suffering from injured, diseased or under-developed intestines (claim 3), wherein the mammal is a pre-term infant having an under-developed intestine (claim 4), wherein the protein is hydrolyzed (claims 5 and 6) and having the various molecular weights recited in claim 7, wherein the protein source provide energy of the nutritional composition thereof (claims 8, 11 and 14), wherein the nutritional composition further includes a lipid source (claims 9, 12 and 15) and wherein the nutritional composition includes a carbohydrate source (claims 10, 13 and 16) .

WO 98/54985 discloses a nutritional composition comprising a protein source including whey protein and a protein mixture having the amino acid profile of whey protein which is administered to stressed patients to increase the plasma glutamine concentration, or administered as nutritional support for increasing muscle glutamine concentration in athletes after exercise, or administered to patients suffering from injured or diseased intestines or to maintain the physiological functions of the intestines particularly in under-developed intestines (e.g., a pre-

term infant or babies). See e.g., page 1, lines 14-34; page 4, lines 3-36; and page 8, lines 23-33. Thus, clearly meeting the limitations of claims 1-4. The prior art discloses the use of nutritional composition wherein the whey protein is hydrolyzed whey protein, the protein source provides about 15% to about 30% of the energy of the nutritional composition, the nutritional composition further includes a lipid source which provides about 20% to about 40% of the energy of the nutritional composition and the lipid source comprises a mixture of medium chain and long chain fatty acids and as such meet the limitations of claims 5-6, 8-9, 11-12 and 14-15.

The reference discloses also a nutritional composition which further includes a carbohydrate source which provide about 35% to about 60% of the energy of the nutritional composition and a such meets the limitations of claims 10, 13 and 16. See e.g., page 3, lines 13-26; page 5, lines 29 to page 6, lines 34; and Examples 2-4. Hence, the reference clearly discloses the administration of nutritional composition which contains whey protein (or a protein mixture which stimulates its acid profile) as a protein source for increasing glutamine levels in plasma or muscle of a stressed patient, pre-term baby or athlete. Thus, as the whey protein hydrolysate comprises glutamine and it is used fro nutritional purposes, it increases plasma glutamine concentration in mammals, increases muscle glutamine concentration in mammals, and provides treatment to patients suffering from injured, diseased or underdeveloped intestines.

In regard to the molecular weight of claim 7, the molecular weight is not disclosed in the prior art; however, the claim as drafted recites any hydrolysate whey protein having a molecular weight which is less than 1,000 Da or having a molecular weight of 1,000 Da to 5,000 Da or a

molecular weight greater than 5,000 Da; and does not define the molecular wight as functional limitation, rather, the claim defines the molecular weight as properties of the hydrolysate whey protein formulation. Thus, it is the Examiner's position that the hydrolysate whey protein formulations of the prior art would have the same molecular weight as claimed (i.e., less than 1,000 Da or greater than 5,000 Da) because the claim does not identify specific protein(s) having a molecular weight greater than 5,000 Da, or fragments thereof having a molecular weight less than 1,000 Da, and as such, the molecular weight is an inherent properties of the prior art protein. Therefore, in the absence of evidence to the contrary, the nutritional formulation and its use thereof as disclosed by the reference anticipates claims 1-16 as drafted.

ACTION IS FINAL, NECESSITATED BY AMENDMENT

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CONCLUSION AND FUTURE CORRESPONDENCE

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Mohamed/AAM

October 31, 2002

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600